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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/767,476	01/28/2004	John R. Stuelpnagel	ILLINC.59CPCPC1	5069
20995 7590 08/21/2008 KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614				
EXAMINER STEELE, AMBER D				
ART UNIT		PAPER NUMBER		
1639				
NOTIFICATION DATE		DELIVERY MODE		
08/21/2008		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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# Office Action Summary

**Application No.**

10/767,476

**Applicant(s)**

STUELPNAGEL ET AL.

**Examiner**

Amber D. Steele

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 29-75 is/are pending in the application.
- 4a) Of the above claim(s) 60-75 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29-59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1448 or PTO-889)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Inventor's Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 1-28 were canceled and new claims 29-50 were added in the preliminary amendment received on January 28, 2004.

In the amendment to the claims received March 9, 2007, claims 29 and 41 were amended and new claims 51-58 were added.

In the amendment to the claims received on October 29, 2007, claims 29, 41, 51, and 55 were amended and new claims 59-75 were added.

The amendment to the claims received on May 23, 2008 amended claims 29, 36-41, 46-51, and 55.

Claims 29-75 are currently pending.

Claims 29-59 are currently under consideration.

### ***Election/Restrictions***

2. Since applicant has received an action on the merits for the originally presented invention (i.e. Group I claims 29-59), this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 60-75 are withdrawn from consideration as being directed to non-elected inventions. See 37 CFR 1.142(b) and MPEP § 821.03.

3. This application contains claims 60-75 drawn to nonelected inventions. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

***Priority***

4. The present application claims status as a CON of 09/606,369 filed June 28, 2000 which is a CIP of 09/473,904 filed December 28, 1999 (issued as U.S. Patent 6,858,394 on February 22, 2005) which is a CIP of 09/256,943 filed February 24, 1999 (issued as U.S. Patent 6,429,027 on August 6, 2002) which claims benefit of 60/113,968 filed December 28, 1998.

***Invention as Claimed***

5. An array of arrays comprising (a) a first substrate with a surface comprising a plurality of assay wells comprising samples and (b) a second substrate comprising a plurality of projections, each projection comprising an array location, each array location comprising a plurality of discrete sites, wherein said sites comprise different bioactive agents, and wherein said plurality of projections is configured to be dipped from above into said plurality of assay wells comprising samples and variations thereof.

6. “Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim.” *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969). Furthermore, “[i]nclusion of material or article worked upon by a structure being claimed does not impart patentability to the claims.” *In re Young*, 75 F.2d 996, 25 USPQ 69 (CCPA 1935) (as restated in *In re Otto*, 312 F.2d 937, 136 USPQ 458, 459 (CCPA 1963)). An apparatus must be distinguished from the prior art in terms of structure rather than function. See *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997); *In re Swinehart*, 439 F.2d 210, 212-13, 169 USPQ 226, 228-29 (CCPA 1971); *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA 1959); and *Hewlett-*

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*Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990). See also MPEP § 2114 and § 2115. Thus, the samples are not provided patentable weight. In addition, the functional language “dipped from above” is not provided patentable weight. However, the structural information gleaned from the reagents and the functional limitations are provided patentable weight (i.e. first substrate must have the ability to hold samples; second substrate must be able to fit within the first substrate, etc.).

#### **Withdrawn Rejections**

7. The rejection of claims 29-30, 35, 37-39, 41, 45, 47-49, and 51-59 under 35 U.S.C. 102(b) as being anticipated by Pinkel et al. WO 97/27326 published July 31, 1997 (provided by applicants in the IDS submitted October 29, 2007) is withdrawn in view of the claim amendments received on May 23, 2008.
8. The rejection of claims 29-59 under 35 U.S.C. 103(a) as being unpatentable over Walt et al. U.S. Patent 6,406,845 filed May 5, 1997; Kercso et al. U.S. Patent 6,132,685 filed August 10, 1998; and Walt et al. U.S. Patent 6,327,410 filed September 11, 1998 (effective filing date of March 14, 1997) is withdrawn in view of the claim amendments received on May 23, 2008.
9. The rejection of claims 29-59 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 7-9, 12-18, 24, 25, 26, 27, 28, 29, and 30 of U.S. Patent No. 6,429,027 is withdrawn in view of the terminal disclaimer filed on May 23, 2008. It is also noted that applicants filed a terminal disclaimer for U.S. Patent 7,166,431.

10. The provisional rejection of claims 29, 35, 39-41, 45, and 49-58 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 and 16-23 of copending Application No. 10/363,240 is withdrawn in view of the claim amendments received on May 23, 2008.

**New Rejections Necessitated by Amendment**

***Claim Rejections – 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 29-38, 40-48, 50-53, 55-57, and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michael et al., 1998, Randomly Ordered Addressable High-Density Optical Sensor Arrays, Analytical Chemistry, 70: 1242-1248; Rushbrooke et al. U.S. Patent 6,646,272 (effective filing date of July 4, 1997); and Tsien et al. U.S. Patent 7,142,290 (effective filing date of July 17, 1998).

For present claims 29-30, 35-38, 40-41, 45-48, 50-53, 55-57, and 59, Michael et al. teach fiberoptic sensor arrays comprising bundles of fiberoptics wherein each fiber is etched to create a well in which a microsphere with bioactive agents including alkaline phosphatase, biotin, and avidin is placed; wherein a 1000  $\mu\text{m}$  fiberoptic bundle can contain approximately 20,600 optical fibers (i.e. potentially 20,600 wells with microspheres comprising bioactive agents) or nanowell arrays with a packing density of greater than  $4.4 \times 10^9$  wells/ $\text{cm}^2$ ; and if more sensors are required, arrays can be bundled (please refer to the entire reference particularly Figures 1-7;

Materials and Methods; Results and Discussion). In addition, Michael et al. teaches that fiberoptic bundles can be dipped from above into a sample well (e.g. hybridization chamber; room to stir, etc.; please refer to the entire specification particularly Figure 1).

However, Michael et al. does not specifically teach multiple sample wells or a substrate with a plurality of fiber optic bundles.

Fore present claims 29-33, 41-43, 51-53, 55-57, and 59, Rushbrooke et al. teach an array of fiber optic bundles (i.e. fiber optic bundles held in position via a coupling plate) corresponding to an array of assay wells wherein the correlation can be one to one (i.e. one assay well, one fiber optic bundle), microtiter plates with 96 or 384 wells are utilized, and x-y-z movement of the both the plate and fiber optic bundles is possible (please refer to the entire specification particularly Figures 4A, 7, 10-14; columns 1-4, 7-9, 11-14).

However, Rushbrooke et al. does not teach a microtiter plate with 1536 wells.

For present claims 34 and 44, Tsien et al. teach micro titer plates ranging from 96 wells to 3456 wells wherein multiple fiber optic bundles can be arranged in a holder (please refer to the entire specification particularly Figures 2-3, 5-7; paragraph spanning columns 4-5; column ).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the fiber optic arrays taught by Michael et al. with the multiplexing (i.e. one well to one fiber optic bundle ratio) taught by Rushbrooke et al. and the larger plate taught by Tsien et al.

One having ordinary skill in the art would have been motivated to do this because both Rushbrooke et al. (see column 1) and Tsien et al. (see columns 1-2) teach that utilizing multiple fiber optic bundles to analyze multiwell plates is advantageous (i.e. saves time, better analysis in

small and closely packed multi-well plates). In addition, Michael et al. teach the advantages of coupling the use of fiber optic bundles as both detectors and substrates for target deposition (i.e. high-throughput, cost effective; see the Introduction).

One of ordinary skill in the art would have had a reasonable expectation of success in the modification of the fiber optic arrays taught by Michael et al. with the multiplexing (i.e. one well to one fiber optic bundle ratio) taught by Rushbrooke et al. and the larger plate taught by Tsien et al. because of the results obtained by Michael et al. (i.e. utilizing fiber optic bundles as substrates and detectors; Figure 6).

In addition, the claims would have been obvious because the substitution of one known element (i.e. single well, single tube or single fiber optic bundle taught by Micheal et al.) for another (i.e. multiwell plate comprising up to 3456 wells or multiple fiber optic bundles taught by Rushbrooke et al. and Tsien et al.) would have yielded predictable results (i.e. scaling up of analysis; high-throughput) to one of ordinary skill in the art at the time of the invention. See *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007).

Therefore, the modification of the fiber optic arrays taught by Michael et al. with the multiplexing (i.e. one well to one fiber optic bundle ratio) taught by Rushbrooke et al. and the larger plate taught by Tsien et al. render the instant claims *prima facie* obvious.

13. Claims 29-35, 37-39, 41-45, 47-49, and 51-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pinkel et al. WO 97/27326 published July 31, 1997 (provided by applicants in the IDS) and Kuebler et al. U.S. 6,519,032 (effective filing date of April 3, 1998).



For present claims 29-30, 41, 53, 57, and 59, Pinkel et al. teach a first substrate comprising a plurality of assay wells comprising targets (i.e. molecules to be attached to the fiber optic strands) or probes (i.e. samples; hybridization chamber) and a second substrate comprising a plurality of array locations comprising a plurality of projections (i.e. fiber optic bundles and/or individual fiber optic strands) comprising different biological binding partners (i.e. bioactive agents) which can be “dipped” into the wells (i.e. room for three dimensional movement by hand; please refer to the entire specification particularly the abstract; Figures 1-5 and 6A-6B; pages 4-7 and 10-20). In addition, after the initial attachment of targets to a fiber optic bundle Pinkel et al. teach that fiber optic strands with differing binding partners can be rebundled into a fiber optic bundle comprising different targets. Please refer to MPEP § 2114 which states that the manner of operating a device does not differentiate an apparatus from the prior art (i.e. moved in three dimensions).

For present claims 35 and 45, Pinkel et al. teach biological binding partners including nucleic acids, nucleic acid analogs, antigens, antibodies, etc. (please refer to the entire specification particularly the abstract; pages 1, 4, 6, and 9).

For present claims 37-38 and 47-48, Pinkel et al. teach fiber optic sensors comprising 30,000 nucleic acids, fiber optic sensors with diameters of 5-500 micrometers, 1000-3000 fiber optic strands in a fiber optic sensor 0.5 mm in diameter, 1 million strands per square millimeter, and approximately 30,000 different biological binding partners per square millimeter (i.e.  $1\text{ cm}^2 = 300,000$  different bioactive agents; please refer to the entire specification particularly pages 8 and 11).

For present claims 39, 49, 54, and 58, Pinkel et al. teach various methods of coupling the bioactive agents with the fiber optic strands including photolithography (i.e. direct coupling; please refer to the entire specification particularly pages 3 and 15-18).

For present claims 51 and 55, Pinkel et al. teach fiber optic bundles (i.e. "sticks"; please refer to the entire specification particularly Figures 2, 4, 5). Please note: the functional limitation (i.e. intended use) of stirring the sample is not provided patentable weight. Please refer to MPEP § 2106 section II. Language that suggests or makes optional but does not limit a claim to a particular structure does not limit the scope of a claim or claim limitation (i.e. intended use). Also refer to MPEP § 2114 which states that the manner of operating a device does not differentiate an apparatus from the prior art.

For present claims 52 and 56, Pinkel et al. teach the transmission faces of the optical fibers attached to a detector and cladding of the optical fibers (i.e. molded; please refer to the entire specification particularly Figure 4; pages 11 and 13-14).

However, Pinkel et al. does not teach a substrate with a plurality of fiber optic bundles or microtiter plates.

For present claims 29-34, 41-44, and 59, Kuebler et al. teach two or more sample holders (e.g. microtiter plates; multiple 96 well plates), a probe head comprising an array of two or more fiber optic probes wherein the fiber optic probes can be adapted for immersion into liquid samples, and stages or robotic arms to move the samples holders and probe heads (please refer to the entire specification particularly Figures 2, 3A-3B, 4A-4C, 5-8; columns 6-7, 15-18, 22).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the fiber optic arrays taught by Pinkel et al. with the multiplexing (i.e. multiple wells, multiple fiber optic bundles) taught by Kuebler et al.

One having ordinary skill in the art would have been motivated to do this because Kuebler et al. (see columns 1-2) teach that utilizing multiple fiber optic bundles to analyze multiwell plates is advantageous (i.e. high-throughput analysis saves time). In addition, Pinkel et al. (see page 2) teach the advantages of coupling the use of fiber optic bundles as both detectors and substrates for target deposition (i.e. analyzing small sample volumes).

One of ordinary skill in the art would have had a reasonable expectation of success in the modification of the fiber optic arrays taught by Pinkel et al. with the multiplexing (i.e. multiple wells, multiple fiber optic bundles) taught by Kuebler et al. because of the results obtained by Pinkel et al. (i.e. utilizing fiber optic bundles as substrates and detectors; Figures 18A-18B, 19-33).

In addition, the claims would have been obvious because the substitution of one known element (i.e. single well, single tube or single fiber optic bundle taught by Pinkel et al.) for another (i.e. multiwell plate or multiple fiber optic bundles taught by Kuebler et al.) would have yielded predictable results (i.e. scaling up of analysis; high-throughput) to one of ordinary skill in the art at the time of the invention. See *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007).

Therefore, the modification of the fiber optic arrays taught by Pinkel et al. with the multiplexing (i.e. multiple wells, multiple fiber optic bundles) taught by Kuebler et al. render the instant claims *prima facie* obvious.

***Conclusion***

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Future Communications***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amber D. Steele whose telephone number is 571-272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ADS

August 12, 2008

/JD Schultz, PhD/

Supervisory Patent Examiner, Art Unit 1635